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EXAMINER

KWAK, DEAN P

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,564	Applicant(s) MAGNALDO ET AL.	
	Examiner Dean Kwak	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/07/2010 has been entered.

Claim Objections

2. Claim 12 is objected to because of the following informalities: recitation "this transparent pipe" in L12 is unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 recites the limitation "the latter" in L1-2. There is insufficient antecedent basis for this limitation in the claim.

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6. Claim 12 recites the limitation "the outlet" in L4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawliszyn (US 4940333) and further in view of Pollema et al. (US 5849592).

Regarding Claims 1 & 12, Pawliszyn teaches a method for analyzing a liquid sample (e.g., concentration gradient detection, see Abstract) by injecting the *sample* in a reaction loop (e.g., sample chamber, Fig. 12 (90); also see C9/L43 & Fig. 9 (54), Fig. 5 (25)) coupled with illumination means (e.g., probe light beam 93 generated by a laser 94 in Fig. 12, C11/L18; also see LED 66 coupled to optical fiber 67, C9/L58 & Fig. 9; LED 82 coupled to an optical fiber 79 in Fig. 10) and detection means (e.g., optical fibers, C11/L59 & Fig. 12 (97); beam position detector, C9/L60 & Fig. 9 (68); light detector, C10/L29) to record levels of light representative of the characteristics of the sample (e.g., concentration gradient, Abstract & C11/L54-63), said method comprising the following steps:

- filling the reaction loop (see the solvent and sample supplied under pressure by pumps, C9/L49-51) with a minimum volume of the sample (61) to be analyzed, through a first input (60) of a T-shaped (57) branch and its output, said output being connected to said reaction loop (see Fig. 9), this reaction loop forming a transparent pipe (C5/L48-49), with which detection means are coupled,
- injecting at least one fixed volume of at least one reagent (e.g., solvent 59) into the reaction loop via a second input (58) of the T-shaped branch and its output to obtain a mixture of the sample with the reagent(s),
- illuminating the transparent pipe with the illumination means (C11/L13-21 & C11/L54-63),

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- filtering the light transmitted through the transparent pipe (see the system using an optical filter 50, C9/L24-27),
- recording levels of light transmitted through said transparent pipe by the detection means after filtering, thereby revealing the characteristics of the sample (see C9/L8-27 & C12/L10-24), and
- discharging the reagents located in the reaction loop (see tubing 62, 63 leads to waste, C9/L51-55).

Regarding Claims 1 & 12, Pawliszyn fails to teach the length of a transparent pipe or the flow rate. While Pawliszyn does not explicitly disclose the transparent pipe with a length between about 0.5 cm and about 10 cm or the flow rate of about 10 to about 1,000 $\mu\text{L}/\text{min}$, the change in the pipe length or the flow rate are not considered to confer patentability to the claims. Pawliszyn utilize optical detection system to develop concentration gradient of specific chemical compounds (Abstract) where various changes may be made in adapting to different design requirements (C12/L65-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the pipe dimensions and the flow rate so that enough retention time required to mix the sample and therefore, accurate detection can be achieved. Therefore the pipe length and the flow rate are a variable that can be modified, among others, by varying the pipe used and changing the flow rate. For that reason, the pipe length and the flow rate would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the pipe length or the flow rate cannot be considered critical. Accordingly, one of ordinary skill in the art

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at the time the invention was made would have modified, by routine experimentation and optimization, the system of Pawliszyn to have a transparent pipe with a length between about 0.5 cm and about 10 cm and a flow rate of about 10 to about 1,000 $\mu\text{L}/\text{min}$ (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding Claims 1 & 12, Pawliszyn fails to teach using a push-syringe.

Pollema et al. teach a flow-injection analysis system (Abstract) for analyzing a liquid sample comprising:

- a reaction loop (e.g., reaction coil, Fig. 4A (RC), C4/L49) between the sample introduced through an inlet (see valve (MPV) inlet in Fig. 4A) and at least one reagent (e.g., reagent, (R), C4/L52), and
- detection means (e.g., flow-through detector, Figs. 1-4 (D), C2/L53 & colorimeter, potentiometer, Claims 5 & 6, respectively)), wherein the reaction loop consists of a transparent pipe, and
- said system comprises a push-syringe (e.g., syringe pump, Figs. 3A & 4A (SP)),
- the outlet (see valve (MPV) in Fig. 4A connecting to the (RC)) of which is connected to the transparent pipe allowing doses of said at least one reagent to be delivered into this loop,
- illumination means with which this transparent pipe may be illuminated (see a colorimeter being used, Claim 5); and

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- a push-syringe (e.g. syringe pump, Figs. 3A & 4A (SP)).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Pawliszyn to use a syringe pump, as taught by Pollema et al., since a syringe pump allows to accurately control low flow rate as well as ability to be operated under computer control, as disclosed by Pollema et al., see C5/L43-58.

Regarding Claims 2-11, 13-15 & 17, modified Pawliszyn further teach the method, wherein:

- a concentration gradient is detected in the reaction loop (see Abstract);
- the reaction loop is a transparent capillary channel (e.g., capillary tube, C9/L41 & Fig. 9 (51); also see the tube having transparent sides, C5/L49);
- the discharge of the reagents located in the reaction loop is performed by means of the remaining sample (C9/L51-55);
- the discharge of the reagents located in the reaction loop is performed by means of the next sample (C6/L33-35);
- the sample flux is not interrupted, which allows continuous analysis (C6/L35-46);
- fixed volumes of reagents are successively injected during predefined time intervals (C6/L33-46);
- a series of pulses of reagents is produced (C6/L33-46);

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- linear detection is performed along the reaction loop (see the optical fibers Fig. 12 (97), Fig. 10 (79, 83) placed linearly along the “reaction loop” to obtain concentration gradient curve as shown in Fig. 7);
- a point detection (e.g., optical fibers, Fig. 12 (97), C11/L59; Fig. 10 (79 & 83), C10/L26 & 30) is achieved in a location of the reaction loop;
- a point sensor is used, and wherein the point sensor is configured to be movable along the reaction loop (C5/L54).
- the transparent pipe is a transparent capillary or a microfluidic channel (e.g., capillary tube, C9/L41 & Fig. 9 (51); also see the tube having transparent sides, C5/L49);
- the detection means comprise a diode array (e.g., photodiode detector, C10/L50);
- the detection means comprise two optical fibers (e.g., optical fibers, Fig. 12 (97), C11/L59; Fig. 10 (79 & 83), C10/L26 & 30) positioned on either side of the reaction loop; and
- a microvalve (e.g. valve, Fig. 9 (57)) positioned upstream from the point of introduction of the sample into the reaction loop.

Regarding Claim 8, Pawliszyn fails to teach the flow rate. While Pawliszyn does not explicitly disclose the flow rate of about 10 to about 1,000 $\mu\text{L}/\text{min}$, the flow rate is not considered to confer patentability to the claims. Pawliszyn utilize optical detection system to develop concentration gradient of specific chemical compounds (Abstract) where various changes may be made in adapting to different design requirements (C12/L65-68). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to adjust the flow rate so that enough retention time required to mix the sample and therefore, accurate detection can be achieved. Therefore the flow rate is a variable that can be modified, among others, by varying the flow rate. For that reason, the flow rate would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the flow rate cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have modified, by routine experimentation and optimization, the system of Pawliszyn to have a flow rate of about 10 to about 1,000 $\mu\text{L}/\text{min}$ (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding Claim 11, although Pawliszyn teaches the optical fibers are glued, it is noted that gluing can be unglued to relocate the detector to another position. In this instance, the claim only requires the ability of the component to be movable, but does not limit the manner in which is it movable. Absent any particular claim language to a use of a structure to move the point sensor, the language of “configured to be movable” is read as merely the ability to do so, thereby an act of gluing and ungluing encompasses a configured ability to meet the limitation.

Regarding Claim 16, Pawliszyn fails to disclose a peristaltic pump.

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Pollema et al. further teach the flow-injection analysis system comprising a peristaltic pump allowing introduction of the sample (C1/L49-50, Figs. 1A-2B (PP)).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a peristaltic pump, as taught by Pollema et al., since a peristaltic pump allows liquid to flow in both directions as well as ability to be operated under computer control, as disclosed by Pollema et al., see C5/L43-55.

Response to Arguments

11. Applicant's arguments filed 06/07/2010 have been fully considered but they are not persuasive. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

12. In response to Pawliszyn fails to teach detecting filtered light, the reference teaches a use of a filter in front of a detector, see C9/L23-27. The reference further teaches the optical fibers 97 for concentration gradient measurement, C11/L54-63.

13. Regarding argument that glued component is not movable, it is noted that gluing can be unglued to relocate the detector to another position. In this instance, the claim only requires the ability of the component to be movable, but does not limit the manner in which is it movable. Absent any particular claim language to a use of a structure to move the point sensor, the language of "configured to be movable" is read as merely the ability to do so, thereby an act of gluing and ungluing encompasses a configured ability to meet the limitation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dean Kwak whose telephone number is 571-270-7072. The examiner can normally be reached on M-TH, 5:30 am - 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

24 July 25, 2010

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/D. K./
Examiner, Art Unit 1797